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Saliwanchik, Lloyd & Saliwanchik 2421 NW 41st Street Suite A-1 Gainesville, FL 32606-6669		EXAMINER COLLINS, CYNTHIA E		
		ART UNIT PAPER NUMBER		
		1638		

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/334,163	Applicant(s) NAGEL, BRUCE	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,10,11,16,18-22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,10,11,16,18-22,24 and 25 is/are allowed.
- 6) ☒ Claim(s) 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>0704</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

Applicant's submission filed on May 20, 2004 has been entered.

Claims 24 and 26 are currently amended.

Claims 7-9, 12-15, 17 and 23 are cancelled.

Claims 1-6, 10-11, 16, 18-22 and 24-27 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn.

An Examiner's amendment canceling claims 26 and 27 was telephonically proposed to Applicant's representative, but was declined.

Claim Objections

Claim 20 is objected to because of the following informalities: claim 20 depends from claim 6 (a product), rather than claim 16 (a method) from which it previously depended. The change in dependency appears to be inadvertent, given that claim 20 is presented here as "previously amended". Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 26 and 27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record set forth in the office action mailed February 17, 2004.

Applicant's arguments filed May 20, 2004 have been fully considered but they are not persuasive.

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Applicant argues that the rejected claims are in compliance with the Written Description Guidelines cited by the Examiner, and Applicant points in particular to the statement in the Guidelines that

In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. Guidelines at 1106

Applicant argues that the Examiner has not provided any evidence or reasoning that explains why this portion of the Guidelines is inapplicable to the rejected claims, and specifically that the Examiner has not provided any evidence that the technology covered by the present claims is in its infancy or that the level of skill in the art is low. Applicant asserts that this is not surprising, since a model for breeding hybrid corn was proposed as early as 1918 and the single cross hybrid model became the predominant model in the 1960s, and since a corn breeder typically has one or more advanced degrees and 5 or more years of experience. Applicant argues that in the absence of any explanation why this portion of the Guidelines is irrelevant, it is submitted that the claims are in compliance with the Guidelines, as well as the written description requirements of the first paragraph of 35 U.S.C. (reply pages 5-7).

The Examiner has not asserted that the technology covered by the present claims is in its infancy, or that the level of skill in the art is low, or that this portion of the Guidelines is irrelevant to the claimed invention, as the outstanding rejection was not predicated on the state of the art or the level of skill in the art. The outstanding rejection was predicated on the failure to disclose the characteristics by which the claimed products may be identified, as set forth at pages 2-3 of the office action mailed June 17, 2003. In this respect the cited portion of the Guidelines is relevant to the subject matter of the rejected claims, because the function of the claimed

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invention, an identifying characteristic, is not disclosed. The rejected claims are directed to F1 hybrid seed and plants produced by the method of claim 24, i.e. by crossing a plant according to claim 6 with a different inbred parent corn plant. While the functional characteristics of a plant according to claim 6 are disclosed, the functional characteristics of F1 hybrid seed and plants produced by the method of claim 24 are not disclosed. Since breeding techniques like the one set forth in claim 24 can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly variable, and since only one F1 hybrid parental line is disclosed (a plant according to claim 6), the functional characteristics of F1 hybrid seed and plants produced by the method of claim 24 are not described.

Applicant also points in particular to the statement in the Guidelines that relates to inventions in emerging and unpredictable technologies:

Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied. Guidelines at 1110 n. 52

Applicant argues that the outstanding Office Actions do not indicate the existence of any barriers that might exist to “actually” using the method of claim 24 to produce the product-by-process of claim 26, i.e., crossing an inventive corn plant belonging to a corn line selected from the group consisting of LS0414, LS1498 and LS288 with a different inbred parent corn plant to produce first generation hybrid corn seed. Applicant asserts that this is also not surprising, since such steps, and therefore such a product, are well within the purview of a person having ordinary skill in this art. Applicant asserts that the Examiner has not explained why the quoted portion of the Guidelines at 1106 is not controlling the present case, or why the Guidelines at 1110 n. 52 is inapplicable to the rejected claims. (reply page 7)

The outstanding Office Actions do not indicate the existence of any barriers that might exist to “actually” using the method of claim 24 to produce the product-by-process of claim 26, because the outstanding rejection was not predicated on the actual use of the method. The record in fact indicates that claim 24 is allowed. The outstanding rejection was predicated on the failure to disclose the characteristics by which the claimed products may be identified. In this respect the cited portion of the Guidelines is relevant to the subject matter of the rejected claims, because Applicant has not disclosed the products “actually” produced by the claimed method.

Applicant additionally points in particular to the case of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), not previously cited, and points out that under the particular facts of that case, it was determined that a product claim to cDNA encoding human insulin was not adequately described by a disclosure of a cDNA sequence found in rats and a disclosure for only a generalized method for obtaining the human cDNA because:

an adequate written description of a DNA. . . "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. (*Lilly*, 43 USPQ2d at 1404).

Applicant also points out that the patent-in-question in the *Lilly* case had claims to a product, i.e., DNA, and it was found that the product claim to DNA was inadequately described by (1) a description of a product outside the scope of the product claim and (2) only a generalized method of preparing the claimed product. Applicant argues that in contrast, each of the presently rejected claims 26 and 27 are product-by-process-claim. Applicant asserts that the Examiner has not explained why the *Lilly* rationale for product claims is applicable to product-by-process claims, and Applicant further points out that the rejected claims are not directed to DNA. Applicant

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asserts that the Examiner has not explained why the *Lilly* rationale applies to corn breeding. Applicant asserts that as explained above, corn breeding is a mature art and the level of skill in the art is high. Applicant also asserts that unlike *Lilly*, with respect to claims 26 and 27, barriers stand in the way of "actually" obtaining first generation hybrid corn seeds by the method of claim 24. Applicant points out that in *Lilly*, it was found that that a product claim was not adequately described by the description of a product outside the scope of the product claim and only a generalized method of preparing the claimed product, whereas it is factually un rebutted that the present claims are product-by-process claims in the field of corn breeding, the description of F1 hybrid seed and plants in the application is identical to the scope of the product-by-process claim, and no evidence exists on the record that the disclosed method for crossing the inbred parent plants to produce the F, hybrid seed and plants in the application lacks the detail necessary to carry out the method as broadly as claimed. (reply pages 7-8)

With respect to the case of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), not previously cited, the principles of the case are applicable to the instantly rejected claims insofar as the outstanding rejection was predicated on the failure to adequately describe a product. In this regard the Examiner acknowledges that the instantly claimed products (F1 hybrid seed and plants) are different from those at issue in *Lilly* (DNA), and thus would require description by means of structural and functional characteristics different from those possessed by DNA. Nevertheless, the instantly claimed products (F1 hybrid seed and plants), like those in *Lily*, are described by (1) a description of a product outside the scope of the product claim (a plant according to claim 6) and (2) only a generalized method of preparing the claimed product (crossing a plant according to claim 6 with a different unspecified inbred parent corn

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plant and harvesting the resultant first generation hybrid corn seed of undisclosed structure and function).

The Examiner further disagrees with the implication that in *Lily* there was a barrier to obtaining a cDNA encoding human insulin, as it was within the ability of one skilled in the art to obtain a cDNA encoding human insulin using the information disclosed in the *Lily* specification (the method used to obtain the rat cDNA along with the amino acid sequences of human insulin A and B chains). The *Lily* court in fact articulated that whether the claimed product was described was not dependent on whether the patent provided an enabling disclosure:

The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case, providing an enabling disclosure for crossing a plant according to claim 6 with a different inbred parent corn plant does not provide a written description of the resultant first generation hybrid corn seed or plant, which is necessary to provide a written description of the subject matter of claims 26 and 27. The name F1 hybrid seed or plant is not itself a written description of that seed or plant; it conveys no distinguishing information concerning its identity. While the specification provides a process for obtaining F1 hybrid seed and plants, there is no

further information in the specification pertaining to that F1 hybrid seeds' or plants' relevant structural or physical characteristics; in other words, it thus does not describe the claimed F1 hybrid seed and plants. Describing a method of preparing F1 hybrid seed and plants, as the specification does, does not necessarily describe the F1 hybrid seed and plants themselves.

Additionally, with respect to Applicant's assertion that the description of F1 hybrid seed and plants in the application is identical to the scope of the product-by-process claim, the Examiner maintains that F1 hybrid seed and plants are not disclosed therein.

Applicant further argues that the applicable legal standard is whether one having ordinary skill in the art would have recognized from the disclosure a description and possession of the invention defined by the claims, and that the Examiner does not point to anything in the originally filed disclosure which remotely suggests that a corn breeder would not be able to visualize or recognize the identity of the products covered by the product-by-process claims or, for that matter, that a corn breeder would not have recognized from the originally filed disclosure that Applicant had possession of the subject matter of the claimed products-by process.

Applicant also points out that the same prior patent cited by the Examiner in the present case, namely U.S. Patent No. 5,569,820 to Stelpflug, contains claims to hybrid seed and hybrid plants.

Applicant also asserts that merely alleging that no phenotypic or genotypic information is included in the claims does not satisfy the Examiner's burden. Applicant argues that it is therefore inconceivable that one having ordinary skill in the art would not have recognized from Applicant's originally filed disclosure a description of the invention defined by the claims,

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particularly in view of the cited issued U.S. patent that contains essentially the same terminology in the same field. (reply page 9)

With respect to a corn breeder being able to visualize or recognize the identity of the products covered by the product-by-process claims from the originally filed disclosure, the Examiner maintains that one skilled in the art could not visualize or recognize the identity of the products covered by the product-by-process claims from the originally filed disclosure, as the identifying characteristics of the products covered by the product-by-process claims are not described the originally filed disclosure, with respect to genetic complement or morphological traits.

With respect to Applicant's possession of the subject matter of the claimed products-by process, the Examiner maintains that possession alone is not always sufficient to satisfy the written description requirement.

With respect to the prior patent cited by the Examiner under 35 USC 102/103 in the present case, namely U.S. Patent No. 5,569,820, the Examiner notes that the instant application does not appear to be related to the application that issued as U.S. Patent No. 5,569,820. The Examiner also notes that each application is examined on its own merits according to the legal standards then extant. Since the instant application does not appear to be related to the application that issued as U.S. Patent No. 5,569,820, and since each application is examined on its own merits, Applicant's comments directed to U.S. Patent No. 5,569,820 under 35 USC 112, first paragraph are inapposite.

The Examiner also does not allege that the claimed products are inadequately described due to the failure to include phenotypic or genotypic information in the claims. The Examiner

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alleges that the claimed products are inadequately described due to the failure to include phenotypic or genotypic information anywhere in the specification.

Claim Rejections - 35 USC § 102/103

Claims 26 and 27 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stelpflug et al. (U.S. Patent No. 5,569,820, issued October 29, 1996), for the reasons of record set forth in the office action mailed February 17, 2004.

Applicant's arguments filed May 20, 2004 have been fully considered but they are not persuasive.

Applicant argues that the Examiner's reliance upon *In re Thorpe* is misplaced. Applicant points out that in *Thorpe*, under the particular facts of that case, it was determined by the Board that the applied prior art references disclosed the same product as that claimed but was prepared by a different process. Importantly, *Thorpe* did not contest the determination that the product of his process was different from the prior art product. In affirming the Board's determination, the Court of Appeals for the Federal Circuit noted that:

[t]he examiner compared the product of the prior art, and the product of Thorpe's process described by Thorpe, in accord with the standard examination practice, noting the similarity of reactants, reaction conditions, and properties. (*In re Thorpe*, 227 USPQ at 97).

Applicant argues that the Examiner's reliance upon a decision where the Examiner compared the prior art product with the product covered by the product-by-process claim by noting the similarity of reactants, reaction conditions, and properties, thereby establishing a prima facie

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case is erroneous because, in the present case, the Examiner has ignored the claimed process steps, i.e., the actual inbred plants used as “reactants” in the present claims and has made no comparison between these and the inbred plants disclosed in Stelpflug. Instead, the Examiner chose to rely solely upon the F1 hybrid claim language to the exclusion of the claim language that identifies the inbred parents of the F1 hybrid. Applicant argues that the Examiner's attempt to impress the *Thorpe* rationale on the present case is, therefore, misplaced and clearly erroneous.(reply pages 9-11)

The Examiner disagrees that reliance upon *In re Thorpe* is misplaced. A comparison of the claimed process steps and product with those of Stelpflug, to the extent that such a comparison is possible, was made at page 5 of the office action mailed June 17, 2003:

The claims are drawn to an F1 hybrid seed produced by crossing a corn plant according to claim 6 with another, different corn plant, and to an F1 hybrid plant grown from said seed. Stelpflug et al. teach F1 hybrid corn seed and F1 hybrid plants (columns 19-20 claim 9). While Stelpflug et al. do not teach that their F1 hybrid seed was produced by crossing a corn plant according to claim 6 with another, different corn plant, the claimed F1 hybrid seed and plant would read on any corn F1 hybrid seed or plant, as the claims do not set forth any characteristics that would distinguish them from other corn F1 hybrid seed or plants.

Neither the claims nor the specification identify “another, different corn plant”, or the F1 hybrid seed and plant produced when a corn plant according to claim 6 is crossed with “another, different corn plant”. Accordingly, a side-by-side comparison between the specific components used in, and the particular products obtained by, Applicant's method and the method of Stelpflug is not possible, given the available information.

Applicant also argues that the Examiner's reliance upon *Thorpe* is misplaced because in *Thorpe* the Applicant did not even assert that the product of his process was different from the product of the prior art. In contrast, Applicant submits that it is impossible that the claimed first generation hybrid corn seed produced by the method of claim 24, i.e., crossing an inventive inbred parent corn plant selected from the group consisting of LS0417, LS1498, and LS288 with the requisite seed profile with a different inbred parent corn plant and harvesting the resultant hybrid corn seed or an F1 hybrid plant grown from such seed is identical to any Stelpflug hybrid that has Z51284 as one parent, and any other inbred disclosed in Stelpflug as the other parent. Applicant urges the Examiner to appreciate that the exact composite of nuclear genes in a corn plant determines its genotype. Each gene occupies a particular position, or locus, in a specific chromosome and is replicated when the chromosome divides. The contrasting forms, called alleles encode for contrasting form of the character. With respect to the genotype of a first generation hybrid corn plant obtained by crossing two inbred parent plants, 50% of the alleles in the genotype of the hybrid plant are obtained from each inbred parent corn plant. The first generation hybrid corn seed of claim 26 is obtained by, inter alia, crossing an inventive inbred parent corn plant selected from the group consisting of LS0417, LS1498, and LS288 with the requisite seed profile and a different inbred parent corn plant. As a result, the genotype of the resulting first generation hybrid corn seed includes 50% of the alleles from inbred corn plant LS0417, LS1498 or LS288 with the requisite seed profile. Simply stated, no combination of Stelpflug's inbred Z51284 with any of Stelpflug's other disclosed inbreds will result in a first generation hybrid corn seed or plant with a genotype that includes 50% of the alleles from the inventive inbred corn plants. Whether Claim 26 contains a limitation about the genotype or

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phenotype of the F1 hybrids is not relevant to this inquiry. The claimed F1 hybrids cannot be identical to Stelpflug's hybrids. Applicant submits that since Stelpflug cannot disclose first generation hybrids having 50% of the alleles from the inventive inbred corn plant having seed with the requisite profile because Stelpflug fails to disclose inbred corn plant with seed having the claimed profile, Stelpflug does not disclose each feature of the claimed invention. Ergo, the Examiner's rejection under 35 U.S.C. 102, as a factual matter, is clearly erroneous.

The Examiner disagrees that reliance upon *Thorpe* is misplaced. *Thorpe* was cited to establish the principle that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. The Examiner maintains that the record does not clearly establish that the process of making the claimed product distinguishes the claimed products from the products made by Stelpflug's process. The Examiner acknowledges Applicant's assertion that it is impossible that the claimed first generation hybrid corn seed produced by the method of claim 24 is identical to any Stelpflug hybrid that has Z51284 as one parent, and any other inbred disclosed in Stelpflug as the other parent, but maintains that neither Applicant's assertion nor the record sufficiently establish the assertion as fact. It is not apparent from the record that no combination of Stelpflug's inbred Z51284 with any of Stelpflug's other disclosed inbreds would result in a first generation hybrid corn seed or plant with a genotype that includes 50% of the alleles from the inventive inbred corn plants, as neither the alleles of the inventive parental inbred corn plants, nor the alleles of Stelpflug's parental inbred corn plants, are of record. Furthermore, none of the individual alleles or traits of the instant corn inbreds are unique to those

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inbreds. Rather, it is the combination of these alleles and traits that are unique. Such combination is lost upon uncrossing to another corn plant.

The Examiner also notes that the rejected claims do not require that the claimed F1 hybrid seed and plants exhibit “the requisite seed profile”, and the Examiner further notes that the genotypic and phenotypic characteristics of one parent in a cross, such as a plant according to claim 6, are not presumed to be imputed to the offspring of that cross.

The Examiner also disagrees that the rejection as a factual matter is clearly erroneous. In this regard the Examiner notes that claims 26 and 27 were not rejected under 35 U.S.C. 102. Claims 26 and 27 were rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a). The claims were rejected in this manner because there is insufficient information of record with which to evaluate the equivalence, or lack thereof, between the claimed F1 hybrid corn plants and those of Stelpflug. There is insufficient information of record with which to evaluate the equivalence, or lack thereof, between the claimed F1 hybrid corn plants and those of Stelpflug because the claimed F1 hybrid seed and plant would read on any corn F1 hybrid seed or plant, as neither the claims nor the specification set forth any characteristics that would distinguish them from other corn F1 hybrid seed or plants.

Applicant further argues that since the Examiner has failed to provide a factual basis to support the conclusion that one having ordinary skill in the art would have been motivated to modify Stelpflug to arrive at the claimed invention, it cannot be concluded that the Examiner satisfied the initial burden of establishing prima-facie case of obviousness, and that the rejection under 35 U.S.C. 103 is also incorrect.

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The Examiner disagrees that the rejection is incorrect. In this regard the Examiner notes that claims 26 and 27 were not rejected under 35 U.S.C. 103. Claims 26 and 27 were rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a). The claims were rejected in this manner because there is insufficient information of record with which to evaluate the equivalence, or lack thereof, between the claimed F1 hybrid corn plants and those of Stelpflug. There is insufficient information of record with which to evaluate the equivalence, or lack thereof, between the claimed F1 hybrid corn plants and those of Stelpflug because the claimed F1 hybrid seed and plant would read on any corn F1 hybrid seed or plant, as neither the claims nor the specification set forth any characteristics that would distinguish them from other corn F1 hybrid seed or plants. The Examiner maintains that the use of rejections under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) for product by process claims has been approved by the courts, when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim (MPEP 2113). Given that neither the claims nor the specification set forth any characteristics that would distinguish the claimed F1 hybrid seed and plants from other corn F1 hybrid seed or plants, the F1 hybrid corn seed and plants of Stelpflug reasonably appear to be either identical with or only slightly different than the claimed F1 hybrid seed and plants.

Applicant also points out that Stelpflug discloses inbred corn line Z51284, and broadly discloses that the invention also relates to a hybrid corn seeds and plants produced by crossing the inbred line Z51284 with at least one other line. Applicant points out that Stelpflug discloses

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inbred Z51284 in certain hybrid combinations in, for example, Tables 5 and 6. Applicant also points to *Panduit Corp. v. Dennison Mfg. Co.*, 8 10 F.2d 1561, 1597 n. 42, 1 USPQ2d 1593, 1606 n. 42 (Fed. Cir. 1987), where the Court underscored the necessity to resolve patentability issues with a view to the real world, and that it is accordingly necessary to interpret Stelpflug realistically through the eyes of one having ordinary skill in the art. Applicant submits that one having ordinary skill in the art, out in the real world with Stelpflug in hand, would focus on the following shortcomings in Stelpflug. First, no disclosure exists in Stelpflug that inbred corn plant Z51284 even has seed with the profile with a mean saturate content of less than about 7.0%, a mean oleic acid content of at least 64.9%, and a mean linoleic acid content of 24.7% or less, by weight relative to the total fatty acid content of said seed as required by claim 6 in the present application. Claim 26 explicitly requires that the F1 hybrid seed be produced by crossing a plant according to claim 6 with a different inbred parent corn plant. Applicant submits that the Examiner has not explained, and it is not apparent, how Stelpflug's inbred corn plant Z51284 could be crossed with another inbred corn plant disclosed in Stelpflug to obtain an F1 hybrid seed that is obvious from the F1 hybrid seed produced by the method of claim 24. Applicant also submits that whether claim 26 sets forth any characteristics concerning the F1 hybrid seed is immaterial because claim 26 requires that the F1 hybrid seed be obtained by crossing a plant having a seed with a profile set forth in claim 6 and the Examiner has not shown that Stelpflug's seed has an identical or even similar profile for that matter. Because the Examiner has failed to provide a factual basis to support the conclusion that one having ordinary skill in the art would recognize that the F1 hybrid seed and plants, as claimed, are obvious from Stelpflug's disclosed F, hybrids, the rejection is improper and should be withdrawn. Applicant argues that Stelpflug

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provides, at the very best, nothing more than an invitation to try experimenting with Z51284 as a parent in crosses with other inbred parents to obtain a first generation hybrid with the genotype, phenotype and attendant advantages that stem therefrom from the F1 hybrid seed and plants of the present invention having a corn plant belonging to a corn line selected from the group consisting of LS0414, LS1498, and LS288 as a parent, which does not and cannot satisfy the Examiner's burden of showing prima facie case of obviousness. Applicant further argues that the Examiner has failed to show (1) that Stelpflug would have suggested the F1 hybrid seed or plants, as claimed, or (2) a basis in the prior art for a reasonable expectation that such hybrid seed or plants could be successfully obtained.

The Examiner maintains that product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. In the instant case the specific structure implied by the recited steps cannot be ascertained, as neither the claims nor the specification set forth the genetic or morphological characteristics of the second parental line (a different inbred corn plant), or the genetic or morphological characteristics of the F1 hybrid seed and plant produced by crossing a plant according to claim 6 with a different inbred corn plant. Neither are the characteristics of a plant according to claim 6 imputed to the claimed F1 hybrid seed and plant, as the rejected claims do not require that the claimed F1 hybrid seed and plant exhibit any of the characteristics of a plant according to claim 6, and the claimed F1 hybrid seed and plant are not presumed to exhibit such characteristics, because the claimed F1 hybrid seed and plant would receive only 50% of its alleles from a plant according to claim 6, which alleles may or may not impute any or all the characteristics of a plant according to claim 6 to the claimed F1 hybrid seed and plant. Accordingly, it is inapposite that Stelpflug do not disclose a

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plant according to claim 6, or that the Examiner has not shown that Stelpflug's seed has an identical or even similar profile to a plant according to claim 6, as the rejected claims do not require that the claimed F1 hybrid seed and plant be identical or similar to a plant according to claim 6, and the record does not establish that the claimed F1 hybrid seed and plant would be identical or similar to a plant according to claim 6.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Claim 20 is objected to.

Claims 1-6, 10-11, 16, 18-22 and 24-25 are allowed.

Claims 26 and 27 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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